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SERIAL NUMBER	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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08/126,505 09/24/93 ATKINSON

J WU101CIP

EXAMINER
WALSH, S

18N2/0515

ART UNIT PAPER NUMBER

13

1812

DATE MAILED: 05/15/95

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This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

☒ This application has been examined ☒ Responsive to communication filed on 12-19-94 ☐ This action is made final.

A shortened statutory period for response to this action is set to expire 3 month(s), days from the date of this letter.
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

- | | |
|---|---|
| 1. <input type="checkbox"/> Notice of References Cited by Examiner, PTO-892. | 2. <input type="checkbox"/> Notice of Draftsman's Patent Drawing Review, PTO-948. |
| 3. <input type="checkbox"/> Notice of Art Cited by Applicant, PTO-1449. | 4. <input type="checkbox"/> Notice of Informal Patent Application, PTO-152. |
| 5. <input type="checkbox"/> Information on How to Effect Drawing Changes, PTO-1474. | 6. <input type="checkbox"/> _____ |

Part II SUMMARY OF ACTION

1. ☒ Claims 1-32 and 34 are pending in the application.
Of the above, claims 4, 5, 10-12, 19, 20, 25-27 and 34 are withdrawn from consideration.
2. ☒ Claims 33 has have been cancelled.
3. ☐ Claims _____ are allowed.
4. ☒ Claims 1-3, 6-9, 13-18, 21-24 and 28-32 are rejected.
5. ☐ Claims _____ are objected to.
6. ☐ Claims _____ are subject to restriction or election requirement.
7. ☐ This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.
8. ☐ Formal drawings are required in response to this Office action.
9. ☐ The corrected or substitute drawings have been received on _____. Under 37 C.F.R. 1.84 these drawings are ☐ acceptable; ☐ not acceptable (see explanation or Notice of Draftsman's Patent Drawing Review, PTO-948).
10. ☐ The proposed additional or substitute sheet(s) of drawings, filed on _____, has (have) been ☐ approved by the examiner; ☐ disapproved by the examiner (see explanation).
11. ☐ The proposed drawing correction, filed _____, has been ☐ approved; ☐ disapproved (see explanation).
12. ☐ Acknowledgement is made of the claim for priority under 35 U.S.C. 119. The certified copy has ☐ been received ☐ not been received ☐ been filed in parent application, serial no. _____; filed on _____.
13. ☐ Since this application appears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.
14. ☐ Other

EXAMINER'S ACTION

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Part III DETAILED ACTION

1. The Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Art Unit 1812.

2. The amendment filed 19 December 1994 has been entered.

3. Applicant's election without traverse of Group I in Paper No. 11 is acknowledged.

Applicant's election of CR1 in Paper No. 11 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (M.P.E.P. § 818.03(a)).

Applicants do not affirm their telephonic provisional election of species of analog containing short consensus repeats (SCRs) derived from a second, different complement regulating protein, species "A" in the requirement set out in paragraph 2, last Office Action. Applicants now elect the species of analog having defined amino acid substitutions, i.e. species "C" in the requirement set out in paragraph 2, last Office Action. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has

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been treated as an election without traverse (M.P.E.P.
§ 818.03(a)).

Claims 4-7, 9-11, 19-22, 24-26 and 34 had been withdrawn
from consideration after Applicants' telephonic election,
5 paragraph 4 of the last Office Action. In view of Applicants'
revised election in response to the requirement of paragraph 2,
last Office Action, claims 1-3, 6-9, 14-18, 21-24 and 28-32 will
be examined. Claims 4, 5, 10-13, 19, 20, 25-27 and 34 are
withdrawn from consideration as being drawn to non-elected
10 species.

5. In the response to the election of species requirement,
Applicants indicate that species embraced by the instant generic
claims are also embraced by the claims of copending application
15 SN 08/210,266. 37 C.F.R. § 1.78(b) provides that when two or
more applications filed by the same applicant contain conflicting
claims, elimination of such claims from all but one application
may be required in the absence of good and sufficient reason for
their retention during pendency in more than one application.
20. Applicant is required to either cancel the conflicting
claims/subject matter from all but one application or maintain a
clear line of demarcation between the applications. See M.P.E.P.
§ 822.

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6. Applicant's arguments filed 19 December 1994 have been fully considered but they are not deemed to be persuasive.

7. The drawings remain objected to for the reasons of record.

5 Correction is required.

8. The disclosure is objected to because of the following informalities: claim 1, line 18, misspells consensus; claim 16, line 20, misspells consensus. Appropriate correction is
10 required.

9. The following is a quotation of the first paragraph of 35 U.S.C. § 112:

15 The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by
20 the inventor of carrying out his invention.

9a. The specification is again objected to under 35 U.S.C.

§ 112, first paragraph, as failing to provide an adequate written description of the invention. The specification refers to Figure 2 at page 4, lines 10-21, but the Figures do not correspond to
25 the description, thus the described matter is missing. Page 14, lines 12 and 14, has been amended to delete reference to a Figure, but this sentence remains an inadequate description

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because it refers to labelling which is absent from the disclosure.

It is suggested that Applicants file an informal Figure 2A and 2B with proposed corrections in response to this objection.

5 If the proposed drawing corrections supply the elements referred to by the specification, then the inconsistencies between description and figure would be resolved and the objection would be obviated. No new matter should be introduced.

10 9b. The specification is objected to under 35 U.S.C. § 112, first paragraph, as failing to provide an adequate written description of the invention, failing to adequately teach how to make and/or use the invention, i.e. failing to provide an enabling disclosure, and failing to present a best mode of
15 carrying out the invention. The claims are directed to a protein analog of CR1 having "defined" amino acid substitutions in the short consensus repeats wherein the substitution alters the activity of the naturally occurring CR1. It is not clear what is intended by "defined" because this term is given no particular
20 definition or description, and it is therefore not clear how one of skill in the art can know what analog to make or how to make it. The sequence of CR1 and of the DNA encoding it are essential to produce the claimed CR1 analogs, DNA, expression system and to practice the claimed methods. However, the essential sequence of

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the native CR1 protein is not disclosed and thus the invention cannot be practiced from this disclosure. When a claim refers with specificity to positions within a protein, e.g. position 79 as mentioned in claim 9, the position is meaningless without reference to a particular protein sequence. Further, there are several sequences of CR1 in the literature, and Applicants intended positions should be identified with reference to a particular sequence in order to protect not only the preferred embodiment but also to allow identification of the homologous substitutions in the other known sequences. Without the essential protein sequence to identify the intended positions, appropriate DNA codons cannot be changed.

Claims 1-3, 6-9, 13-18, 21-24 and 28-32 are rejected under 35 U.S.C. § 112, first paragraph, for the reasons set forth in the objection to the specification.

Applicants argue that the publications are clearly cited by Applicants and that the DNA sequences encoding the naturally occurring proteins are well known and accessible to any one skilled in the art; that Applicants need not disclose what is known to those skilled in the art, and need disclose only what is new; that just as one does not have to provide the method of synthesis for a commercially available reagent, one should not have to provide the DNA sequence for every imaginable molecule one might choose to practice the invention. The objection has

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been revised in view of Applicants' arguments. It would be sufficient to provide only the CR1 protein sequence because DNA sequences could be deduced from the protein sequence. Since the claims to DNA are written in terms of the protein to be encoded,
5 the protein sequence is critical.

10a. Claim 14 is again rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant
10 regards as the invention.

Applicants request clarification of the rejection. Claim 14 is ambiguous because the intended limitation of "consisting essentially of" is unclear when applied to CR1: CR1 is a polymer having about 30 SCRs but the essential feature of any group of
15 three is not interfered with by the presence of the others; thus a CR1 analog consisting of only three SCRs would not be indistinguishable from a CR1 analog with as many as 30 SCRs when "consisting essentially of" language is used; what degree of open or closed language is intended? Consisting essentially of limits
20 the scope of a claim to the specified ingredients and those that do not materially affect the basic and novel characteristics of a composition. Ex parte Davis et al., 80 USPQ 448 (PTO Bd. App. 1948). Since the claimed composition is a unitary compound, it

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is unclear how the addition of more of the original compound has an effect on the compound.

10b. Claims 1, 2, 8, 9, 13, 16, 17, 23, 24 and 28 are rejected
5 under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 1 and 16 are ambiguous at the last phrase because the antecedent for "protein" is unclear; is it the unmodified protein that
10 binds, or should the last phrase recite "the protein analog binds ...". Claims 1 and 16 are vague and confusing because it is not clear what is intended by the word "defined" in the phrase "defined amino acid substitutions"; no substitutions are defined in the claim. Claims 2 and 17 lack antecedent basis for "the
15 complement regulatory activity", and lack antecedent basis for "decay accelerating activity". Claims 8 and 23 are indefinite because they refer to amino acids 194-253 and amino acids 271-543, but do not identify what SEQ ID NO: is being referenced; position numbers have no meaning without a reference to a
20 particular sequence. Claims 9 and 24 refer to various amino acid positions, e.g. the first is 79, but do not identify what SEQ ID NO: is being referenced; position numbers have no meaning without a reference to a particular sequence. Claims 13 and 28 lack antecedent basis for "decay accelerating activity".

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11. The claims are free of the prior art of record.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Stephen Walsh whose telephone number is (703) 308-2957. The Examiner can normally be reached on Monday-Friday from 8:00AM to 4:00PM. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Garnette D. Draper, can be reached on (703) 308-4232.

Papers related to this application may be submitted to Group 1800 in Crystal Mall 1 by facsimile transmission, in conformity with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The FAX phone number for Art Unit 1812 is (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Stephen Walsh
Stephen Walsh, Ph.D.
Primary Examiner
Group 1800

SW
May 13, 1995